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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,452	05/04/2001	Michael Lassner	02-104910US	8657

30560 7590 03/09/2004

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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/849,452	LASSNER ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95-97,99,104,131 and 132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95-97,99,104,131 and 132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed December 22, 2003. Amendments were made to the claims. Specifically, claims 94, 98, 100-103, 129 and 130 were cancelled.

Claims 95-97, 99, 104, 131 and 132 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 29, 2003, that is not addressed in this action has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 95-97, 99, 104, 131 and 132 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection that is not necessitated by amendment.**

Applicant claims a recombinant biodetector comprising a shuffled R gene that provides enhanced resistance to pathogens or environmental stressors, and a reporter that is operably linked to a promoter that is responsive to the activated R gene. The claims read on a broad genus of shuffled R genes that provide enhanced resistance to pathogens or environmental stressors, which are to be used as a major component of the recombinant biodetector.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a recombinant biodetector comprising a shuffled R gene that provides enhanced resistance to pathogens or environmental stressors by function only, without any disclosed or known correlation between the elements (specifically, the shuffled R genes) and their function (specifically, an enhanced resistance to pathogens or environmental stressors by function only). The specification only provides teachings on how to shuffle genes with the hopes of identifying an R gene having the desired property (i.e., enhanced resistance to pathogens or environmental stressors). However, it is noted that the claimed invention is a product, which requires that the skilled artisan be capable of incorporating a shuffled R gene with the desired property into the biodetector; the invention is not a method for the identification of a shuffled R gene to be used in a recombinant biodetector. In order to envision the product, the skilled artisan must be able to envision the functional components of the product; however, knowing that a product may potentially be randomly generated by a method does not equate to the resulting product being described or envisioned. The instant specification does not teach a representative number of shuffled R genes with the desired properties, nor does the specification teach a

structure-function relationship indicating what shuffled R genes have the structural requirements that are necessary to functionally enhance resistance, such that the skilled artisan can envision the broadly claimed invention which comprises any shuffled R gene that has the property of enhanced resistance to pathogens or environmental stressors. Without the ability to envision which shuffled R genes actually have an enhanced resistance to pathogens or environmental, the skilled artisan cannot envision the larger embodiment of the recombinant biodetector that encompasses such a shuffled R gene.

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one to envision a representative number of shuffled R genes with enhanced resistance to pathogens or environmental stressors by disclosing structural or functional features of the shuffled R gene that confer the enhanced activity so that one of skill in the art could envision the claimed invention. In essence, the prior art teaches that there are methods that may potentially generate such shuffled genes, but there is no description as to what these shuffled genes look like in terms of a structure-function relationship. Thus, the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

In conclusion, it is reiterated that the invention is directed to a product, and this product requires the presence of a shuffled R gene that necessarily has the property of enhanced resistance to pathogens or environmental stressors. As such, the skilled artisan must be able to conceptualize what shuffled R genes have this property in order to envision a recombinant biodetector comprising a functional shuffled R gene. However, there is no indication in the

either the instant specification or prior art as to what shuffled R genes have such a property, nor is there an indication as to the structure-function relationship between an R gene and its ability to confer an enhanced resistance to pathogens or environmental stressors. As a result, the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claims 95-97, 99, 104, 131 and 132 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This is a new rejection that is not necessitated by amendment.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is a product. This product, called a biodetector, comprises a shuffled R gene that confers an enhanced resistance to pathogens or environmental stressors. In order to make the claimed invention, one of skill in the art must be able to make a shuffled R gene that necessarily has the desired property of an enhanced

resistance to pathogens or environmental stressors. It is also noted that the *ability to identify* is not equivalent to the *ability to make.*

Scope of the invention. The scope of the invention is very broad, and encompasses a biodetector comprising any shuffled R gene that has an enhanced resistance to pathogens or environmental stressors.

State of the art. The state of the art as it regards shuffled R genes having an enhanced resistance to pathogens or environmental stressors is virtually silent. There is no description in the prior art of a representative number of shuffled R genes that have an enhanced resistance to pathogens or environmental stressors, nor is there a description of a structure-function relationship between shuffled R genes and the enhanced resistance. In other words, the state of the art provides no guidance as to what shuffled R genes will have the required property because there is no predictable association between the function of enhanced resistance and a structural feature that results from a shuffled R gene. As a result, the skilled artisan would need to consult the instant specification for guidance on how to make a shuffled R gene to be used in the claimed recombinant biodetector.

Number of working examples and Guidance provided by applicant. The instant specification provides very little guidance on shuffled R genes that have an enhanced resistance to pathogens or environmental stressors. There is no description of even a single example of a shuffled R gene that has such an enhanced property, let alone a description of a structure-function relationship for shuffled R genes that necessarily have the enhanced resistance. Rather, the instant specification only provides guidance that there are methods for the shuffling of genes, to be used in the identification of genes with desired properties. However, it is reiterated that the

instant claims are not directed to methods of identifying genes (specifically R genes) with desired properties, but to products that must necessarily have a shuffled R gene with a desired property. In this instance, the ability to identify a shuffled R gene with a desired property (i.e., an enhanced resistance to a pathogen or environmental stressor) is not equivalent to the ability to make a shuffled R gene with a desired property because the claimed product is directed to a biodetector that already has a given property. The need to find something (i.e., a shuffled R gene with enhanced resistance to pathogens or environmental stressors) that can be used in the claimed invention indicates that the ability to make the invention has not been met because all of the required components cannot be made routinely.

Unpredictability of the art and Amount of experimentation required. In the instant case, neither the instant specification nor the state of the art adequately provides guidance so that the skilled artisan can make the claimed invention. Instead, the skilled artisan would be required to practice an undue amount of unpredictable trial and error experimentation in order to make the claimed invention. This is because there is no indication as to which shuffled R genes have the enhanced resistance to pathogens or environmental stressors that is required for their use in the claimed invention. Without this knowledge, the skilled artisan would not be aware of which shuffled R genes to use when making the claimed invention. Rather, the skilled artisan would have to empirically determine which shuffled R genes were acceptable for use in making the claimed invention. Because this experimentation is empirical in nature (meaning that it *relies* on experimental determination), it necessarily represents an undue and unpredictable amount of experimentation.

In conclusion, the skilled artisan must necessarily know what shuffled R genes can be used to make the claimed invention. Without this knowledge, the major component of the claimed biodetector is unknown. Because there is no teaching in either the state of the art or the instant specification to indicate which R genes actually have an enhanced resistance to pathogens or environmental stressors, the skilled artisan would have to empirically determine what components can be used to make the claimed invention. Thus, without the components of the claimed invention being clear, the skilled artisan cannot make the claimed invention, thus the invention lacks enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 95-97, 99, 104, 131 and 132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection that is not necessitated by amendment.**

The term "enhanced" in claim 95 is a relative term which renders the claim indefinite. The term "enhanced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, in order to determine whether or not the shuffled R gene has an "enhanced" resistance, one would necessarily have to compare it to something. In other words, it is not clear what standards are being used when determining

whether or not the shuffled R gene has an "enhanced" activity, therefore it is unclear what is encompassed within the limitations of the claims.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER
PRIMARY EXAMINER